II. REMARKS

Claims 1, 11 to 13, 15 to 22, 24, 28, and 30 to 39 are pending. The Applicants acknowledge that claims 32 to 39 were withdrawn by the Examiner as allegedly being drawn to a non-elected invention. Office Action at page 2. The Applicants reserve the right to file one or more divisional applications on the underlying subject matter. The Applicants thank the Examiner for withdrawal of the objections to the claims and the provisional rejections under the judicially created doctrine of obviousness-type double patenting over co-pending U.S. Pat. Appl. Nos. 10/425,115 and 10/425,114. *Id.*

1. Rejection under 35 U.S.C. § 101

Claims 1, 11 to 13, 15 to 22, 24, 28, 30 and 31 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly is not supported by either a specific, substantial, and credible utility or a well-established utility. *Id.* at page 3. The Applicants disagree.

The Applicants have provided nucleic acid sequences which are shown in the specification to correlate to genes of a known function and proteins involved in the phosphogluconate pathway, namely glucose-6-phosphate 1-dehydrogenase, 6-phosphogluconate dehydrogenase, D-ribulose-5-phosphate-3-epimerase, ribose-5-phosphate isomerase, transketolase, transaldolase, and phosphoglucoisomerase. The specification discloses specific and substantial uses for the claimed nucleic acid molecules including use to identify polymorphisms related to the recited phosphogluconate pathway enzyme (*see, e.g.,* specification at page 67, line 3 through page 74, line 18) and use to transform plants (*see, e.g.,* specification at page 92, line 1 through page 110, line 16). The correlation and uses are sufficient to satisfy the utility standard.

The Examiner appears to be arguing without evidentiary support that the claimed sequences do not encode the maize or soybean phosphogluconate pathway enzymes. At the outset, the Applicants wish to bring the Examiner's attention to the fact that claims 11 to 13, 15 to 21, 30 and 31 do not recite that the claimed nucleic acid molecules encode maize or soybean phosphogluconate pathway enzymes. As discussed above, the claimed nucleic acid molecules exhibit sufficient correlation with glucose-6-phosphate 1-dehydrogenase, 6-phosphogluconate dehydrogenase, D-ribulose-5-phosphate-3-epimerase, ribose-5-phosphate isomerase, transketolase, transaldolase, and phosphoglucoisomerase. Nothing more is needed.

Indeed, the Examiner acknowledges that Table A of the specification indicates that SEQ ID NO: 1 has a 58 percent identity with a glucose-6-phosphate 1-dehydrogenase and the Vosnidou Declaration (filed with the Applicants' previous response) provides evidence that SEQ ID NO:1 has 95 percent identity to a gene that is similar to a glucose-6-phosphate 1-dehydrogenase. Office Action at page 4.

An Examiner must accept a utility by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). "More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion." Federal Register 66(4):1096, Utility Guidelines (2001). "[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d

1895, 1900 (Fed. Cir. 1996). "An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof." M.P.E.P. § 2107.03, at page 2100-43. The disclosure and the Vosnidou Declaration evidence such a reasonable correlation. *See, In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996).

The specification discloses that the enzymes are discrete phosphogluconate pathway enzymes or fragments thereof, for example, SEQ ID NO: 1, glucose-6-phosphate-1-dehydrogenase, SEQ ID NO: 225, D-ribulose-5-phosphate-3-epimerase; and SEQ ID NO: 619, phosphoglucoisomerase. *See, e.g.,* specification at page 14, line 2 through page 15, line 2, page 222, line 8 through page 223, line 13 (Example 4), Table A and the sequence listing. The specification also explains the interrelationship of the respective enzymes involved in the phosphogluconate pathway (*see, e.g.,* specification at page 1, line 17 through page 4, line 20). In addition, the specification also discloses the methods used to analyze each of the claimed nucleic acid molecules and its association with the phosphogluconate pathway. *See, e.g.,* specification at page 15, line 21 through page 20, line 4 and Table A. In contrast, the Examiner has provided no evidence to support that one of skill in the art would conclude that the claimed sequences do not encode peptides or proteins with any activity. Office Action at page 4.

In light of the above, the Applicants respectfully request reconsideration and withdrawal of this rejection.

2. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1, 11 to 13, 15 to 22, 24, 28, 30, and 31 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled because the claimed invention allegedly lacks utility. Office Action at page 5. The Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper and the Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 1, 22, 24 and 28 also stand rejected under 35 U.S.C. § 112, first paragraph, as the claimed subject matter allegedly is "not described in the specification in such a way as to enable one skilled in the art... to make and/or use the invention." *Id.* at page 6. The Applicants respectfully maintain their traversal of this rejection.

The Examiner maintains that "[t]he instant specification does not teach that the claimed nucleic acids are known to encode polypeptides with enzymatic activity" ... and that "none of the claimed nucleic acids appears to be long enough to encode the entirety of any of the enzymes recited in the claims" and that "it is not known whether any encoded fragment of a polypeptide would have enzymatic activity." *Id.* However the Examiner again has not provided any support that the Applicants must provide evidence that any of the claimed nucleic acid sequences do, in fact, encode any peptides, whether having enzymatic activity or not. While such data may be "helpful", they are not legally required.

Further, one of ordinary skill in the art would know how to use the claimed nucleic acids to encode an enzyme. For example, the specification provides a detailed description of the nucleic acid sequences, amino acid sequences, nucleic acid constructs and methods for using

these agents. *See, e.g.*, specification at page 46, line 6 through page 52, line 16 (describing enzymes encoded by the nucleic acid sequences of the present invention, homologues and other modifications, and methods of producing or expressing enzymes, or fragments of enzymes), page 92, line 1 through page 110, line 16 (describing use of the claimed nucleic acid molecules in methods of transforming plants), page 110, line 17 through page 113, line 4 (describing use of claimed nucleic acid molecules in transformation of plants to reduce the expression of phosphogluconate pathway enzymes). Taken in combination, such disclosure provides adequate direction – including working examples – to teach the skilled artisan how to make and use the claimed invention without undue experimentation.

To the extent that any additional experimentation may be required, the performance of routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re. Angstadt,* 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976). Time and difficulty of experiments are not determinative if they are merely routine. M.P.E.P. § 2164.06, page 2100-192. That is, experimentation is not necessarily undue simply because it is complex, if the art typically engages in such experimentation. *See In re Certain Limited-Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174, (Int'l Trade Comm'n 1983) *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 U.S.P.Q. 428 (Fed. Cir. 1985).

In conclusion, the Applicants submit that they have provided considerable direction and guidance, and have presented working examples such that it is well within the level of ordinary skill in the art to practice the invention without undue experimentation. The Examiner has still not provided sufficient evidence to cast doubt on the guidance provided in the specification.

Therefore, the Applicants submit that the claims are fully enabled under 35 U.S.C. § 112, first paragraph, and respectfully request withdrawal of this rejection.

3. Rejection under 35 U.S.C. § 112, first paragraph, Written Description

Claims 1, 22, 24, and 28 were rejected under 35 U.S.C. § 112, first paragraph, because the claimed subject matter allegedly was "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at page 8. The Examiner's position is "that the specification does not in fact, actually describe any nucleic acid KNOWN to encode an entire enzyme, and therefore does not describe nor show possession of the claimed invention of at least claims 1, 22, 24, and 28." *Id.* The Applicants respectfully disagree.

The Applicants reiterate that the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311,

569, and 619, complements, as well as the enzymes, or fragments thereof, that they encode. Therefore, the Applicants have indeed demonstrated possession of the claimed invention.

The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids can be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). The Applicants have satisfied that test for written description. The Examiner has offered no evidence to demonstrate, in light of the Applicants' disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by the Applicants' claims has not been adequately described in the present disclosure. Therefore, the Applicants respectfully submit that claims 1, 22, 24, and 28 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112 and respectfully request reconsideration and withdrawal of this rejection.

III. CONCLUSION

In view of the foregoing remarks, the Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned at 202-942-5746 if any additional information is necessary for allowance.

Respectfully submitted,

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